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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,379	02/07/2006	Sadahiro Iwabuchi	TEI-0137	9654

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EXAMINER	
FERNANDEZ, KATHERINE L	
ART UNIT	**PAPER NUMBER**
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,379	IWABUCHI ET AL.	
	Examiner	Art Unit	
	Katherine L. Fernandez	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/7/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The Information Disclosure Statement filed on April 7, 2006 is acknowledged. The Information Disclosure Statement meets the requirements of 37 C.F.R. 1.97 and 1.98 and therefore the references therein have been considered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-2, 4-5 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duarte (US Patent No. 4,530,360) in view of Lindgren et al. (US Patent No. 6,254,553), and further in view of Haro et al. ("Vascular endothelial growth factor (VEGF)-induced angiogenesis in herniated disc resorption", 2002) and Hadjiargyrou ("Enhancement of Fracture Healing by Low Intensity Ultrasound", 1998).

With regards to claims 1-2, 4-5 and 7-8, Duarte discloses an apparatus and method for promoting bone healing: at least one ultrasonic transducer (80, column 4, lines 3-11); an ultrasonic oscillator (10, column 3, lines 4-14); and the placement of the applicator on the skin of the patient, with an ultrasound transducer directing sound waves to the bone defect to be healed (column 1, lines 37-48). Regarding claims 2, 5,

and 8, Duarte discloses that the ultrasound transducer comprises means for emitting ultrasonic waves having a frequency of 1.3 to 2 MHz (column 2, lines 7-9), a repetition frequency of 100 to 1000 Hz (column 2, lines 9-12), a burst width of 10 to 2000us (column 3, lines 18-21), and power of 1 to 100 mW/cm2 (column 3, lines 28-33).

However, Duarte does not disclose that the apparatus is used for promoting the natural herniated disc resorption (HDR), nor that their apparatus includes means for mounting the ultrasonic transducer to a site of herniated disc.

Lindgren et al. disclose a device that uses ultrasound for the noninvasive treatment of sciatia, particularly the treatment of a herniated intervertebral disc by reduction of the volume of the nucleus pulposus. They disclose that their apparatus comprises of therapeutic ultrasonic transducers that are preferably mounted on a frame that is displaceable relative to the treatment table and the patient for setting the transducers relative to an intervertebral disc to be treated (column 6, lines 1-9). At the time of the invention, it would have been obvious to one of ordinary skill in the art to include a mount means in the apparatus of Duarte. The motivation for doing so would have been to be able to set the transducer in a position suitable for treating the herniated disc, as taught by Lindgren et al. (column 6, lines 1-9).

However, Duarte in view of Lindgren et al. do not specifically disclose that their method and apparatus is for promoting the natural HDR. Haro et al. disclose that MRI studies suggest that herniated disc resorption occurs more frequently in those completely exposed to the epidural space and that this correlates with their degree of vascularization (abstract). Further, they conclude in their study that vascular endothelial

growth factor (VEGF) induction can result in neo-vascularization of the intervertebral disc tissue and may thus play a role in the resorption of HD (i.e. promotion of HDR with increased blood flow) (abstract). Hadjiargyrou et al. disclose that low intensity pulsed ultrasound, as used by Duarte, is used for fracture healing and works by influencing several stages of the healing process, including signal transduction, gene expression, increased blood flow, tissue modeling and remodeling, and the delivery of key components (growth factors) essential to the healing process (abstract; pg. S226, 1st column, paragraph 4 through 2nd column, 2nd paragraph; pg. S223, 3rd paragraph). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the method and apparatus of Duarte in view of Lindgren et al. be used for promoting the natural HDR. The motivation for doing so would have been that low intensity pulsed ultrasound increases blood flow and the delivery of key components, such as growth factors, to the targeted area and an increased degree of vascularity, as taught by Hadijargyrou (pg. S226, 1st column, paragraph 4 through 2nd column, 2nd paragraph; pg. S223, 3rd paragraph), which is known to promote HDR as taught by Haro et al. (abstract).

5. Claims 3,6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duarte in view of Lindgren et al., Haro et al. and Hadijargyrou et al. as applied to claims 1-2, 4-5, and 7-8 above, and further in view of Ito et al. ("Effects of Ultrasound and 1,25-DihydroxyVitamin D3 on Growth Factor Secretion in Co-Cultures of Osteoblasts and Endothelial Cells", 2000).

The above combined references do not specifically disclose that the ultrasonic waves have a frequency of 1.5 MHz, a repetition frequency of 1KHz, a burst width of 200 us, and power of 30 mW/cm2. Ito et al. disclose a study to investigate low-intensity pulsed ultrasound effect on growth factor secretion in co-cultures of osteoblasts and endothelial cells that uses ultrasound signals consisting of 1.5 MHz, 200 us burst sine wave with repeating pulsation at 1.0 kHz, delivered at an intensity of 30 mW/cm. At the time of the invention, it would have been obvious to one of ordinary skill in the art to have used the above discussed parameters. The motivation for doing so would have been that these parameters have been tested successfully in previous clinical studies and were found to be optimal in the study, as taught by Ito et al. (pg. 162, column 2, 3rd paragraph).

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No.10/415470. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims have the same limitations and solely differ in the intended use of the apparatus (i.e. instant claims disclose that their apparatus is used for promoting the natural herniated disc resorption (HDR) and claim of copending Application discloses that their apparatus is used for treating an osteoarthritis, Osgood-Schlattter's disease, or rheumatoid arthritis). It would have been obvious to one of ordinary skill in the art to apply the apparatus of Application 10/415470 to promote the natural herniated disc resorption since it is structurally capable of performing the intended use.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni M. Mantis-Mercader can be reached on (571)272-4740. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER